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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	
First Inventor or Application Identifier	GREGORY GENE STEINER
Title	"Alpha-pyrone compositions for controlling..."
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

JC542 U.S. PTO 09/596362 06/17/00

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)*
(Submit an original and a duplicate for fee processing)

2. [X] Specification [Total Pages 14]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [ ] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 0]

4. Oath or Declaration [Total Pages]
a. [X] Newly executed (original or copy)
b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
i. [ ] DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

*** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).**

5. [ ] Microfiche Computer Program *(Appendix)*

6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. [ ] Computer Readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____
Prior application information: *Examiner* _____ *Group / Art Unit:* _____
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

☐ *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

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Name (Print/Type)	GREGORY GENE STEINER	Registration No. (Attorney/Agent)	
Signature		Date	6-12-00

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional)

Applicant, Patentee, or Identifier: GREGORY GENE STEINER

Application or Patent No.: _____

Filed or Issued: _____

Title: "Alpha-pyrone compositions for controlling craving and as a substitute for alcohol."

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- [X] the specification filed herewith with title as listed above.
- [ ] the application identified above.
- [ ] the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- [X] No such person, concern, or organization exists.
- [ ] Each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

GREGORY GENE STEINER		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of inventor	Signature of inventor	Signature of inventor
6-12-00		
Date	Date	Date

PATENT APPLICATION OF

GREGORY GENE STEINER

FOR

TITLE: ALPHA-PYRONE COMPOSITIONS FOR CONTROLLING CRAVING AND AS A SUBSTITUTE FOR ALCOHOL

CROSS-REFERENCE TO RELATED APPLICATION: Provisional application # 60/141,805 filed 06/29/99

BACKGROUND -Field of the invention

The present invention relates to novel therapeutic compositions comprising at least one alpha-pyrone as the active principal thereof, and to the use of such novel compositions for treating cravings and as a substitute for alcohol.

Description of Prior Art

Biochemical investigation of addiction has focused on the loci of action of the substance of abuse in the brain. A great deal is known about the receptor sites for the substances of abuse. Many drugs have been designed to react with the receptor sites for substances of abuse in an effort to find an effective treatment for addiction. Considerable knowledge has developed regarding the chemicals produced in the synaptic cleft associated with the substances of abuse and the drugs designed to treat addiction. To date a variety of drugs have been developed in an attempt to control the craving of addiction. However, to date no effective anti-craving medication has been developed in light of the fact that treatment of addiction remains psychological in nature.

Addictions to alcohol and drugs cause great physical and financial harm to the addict and to society. Efforts to develop effective treatments for addictions have been unsuccessful. Temperance and legislative efforts to restrict access to drugs and alcohol have failed.

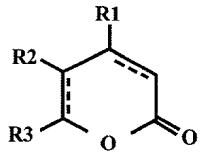
Alpha-pyrones for the treatment of cravings and/or as a substitute for alcohol have no references in prior art.

SUMMARY OF THE INVENTION

A major object of the present invention is the provision of compounds of the alpha-pyrone type for reducing the craving associated with addiction and compulsive behavior. Another significant object of the present invention is the incorporation of an effective amount of alpha-pyrones in non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled spirits as an effective carrier for the anticraving agents.

In addition, an effective amount of alpha-pyrones added to non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled spirits creates a novel alcohol substitute designed to provide the positive effects of alcohol such as stress reduction and anxiety control without the negative health and social effects of alcoholic beverages.

Briefly, the present invention features novel therapeutic compositions for the treatment of the cravings associated with addictions and compulsive behavior comprising in a physiologically acceptable medium, at least one alpha-pyrone having the following structural formula:



in which R1 is a hydrogen atom or an alkoxy radical having 1 to 4 carbon atoms, R2 is a hydrogen atom or a hydroxyl group, and R3 is an alkyl radical having from 1 to 4 carbon atoms or

a styryl or phenethyl radical optionally substituted by one or two methylenedioxy radicals or one or two hydroxyl groups and/or one or two alkoxy radicals having from 1 to 4 carbon atoms, with the proviso that, when R2 is a hydroxyl group, then R3 is necessarily an unsubstituted phenethyl radical, with the future proviso that when R3 is an alkyl radical having 1 to 4 carbon atoms, then R1 and R2 cannot both be hydrogen.

DETAILED DESCRIPTION OF THE INVENTION

The present invention involves administered alpha-pyrones that reduce the cravings of addictions and reduce compulsive behavior. In this invention craving means obsessive compulsion for indulgence in substances that are classed as psychoactive drugs and/or acts which enhances the effect of endogenous and /or exogenous neuropeptides, neorotransmitters and psychoactive agents. Psychoactive drugs include but are not limited alcohol, opiates, stimulants, barbiturates, nicotine and food. Compulsive acts include but are not limited to sexual acts and other compulsive behaviors.

Additionally the invention involves the addition of alpha-pyrones to non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled spirits as an alcohol substitute.

Alpha-pyrones called kavapyrones are naturally found in the kava plant (Piper methysticum). Kava is consumed in order

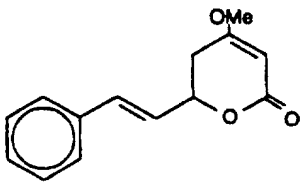
to achieve a relaxed state with a positive mood and a mild euphoria. Kava is intoxicating when large amounts are consumed. However, because kava is nonaddicting (Lebot V. 1992) and does not cause craving or tolerance/dependence, intoxication is essentially unheard-of. The lack of craving and tolerance/dependence results from an effective amount of active alpha-pyrones in kava acting on the dopaminergic neurons of the nucleus accumbens.

The commonly accepted actions of the alpha-pyrones found in kava which are referenced in the literature are as an anti-anxiety agent (Voltz 1997), antidepressant (Warnecke G et al 1998), euphoriant (Baum SS et al., 1998), muscle relaxant (Seitz 1997), analgesic (Jamieson 1990), anticonvulsant (Kretzschmar R 1969) and as a topical treatment for hair loss (US558368). Kava consumption has been found to be directly correlated with a reduction in cancer incidence for a number of South Pacific Nations and is being studied as an effective anticancer agent (unpublished data).

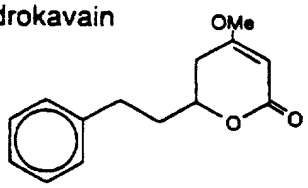
Kavapyrones have become popular in the west as anti-anxiety agents. No side effects have been identified when used on a daily basis in moderate amounts (German Commission E). Years of daily use have been found to cause a dermatologic scaling that is reversed when the drug is discontinued (Norton SA et al., 1994). No irreversible side effects have been noted.

Among the alpha-pyrone compounds comprising the therapeutic compositions of the invention are the following:

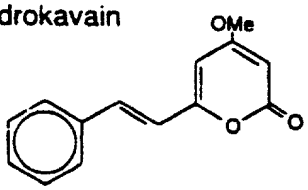
1. Kavain



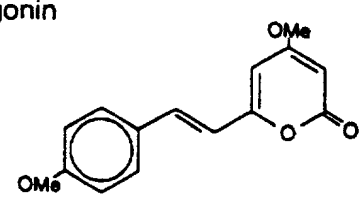
2. 7,8-Dihydrokavain



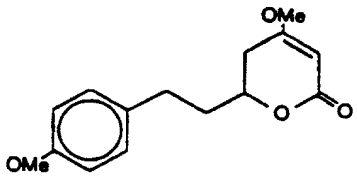
3. 5,6-Dehydrokavain



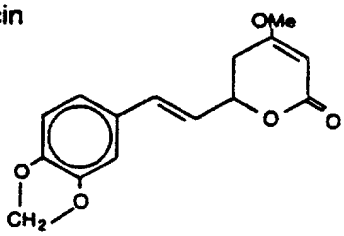
4. Yangonin



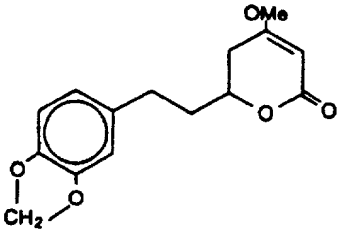
5. 5,6,7,8-Tetrahydroyangonin



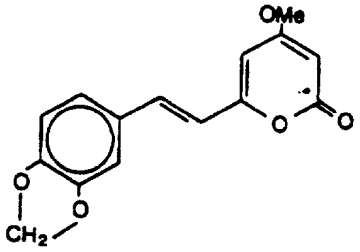
6. Methysticin



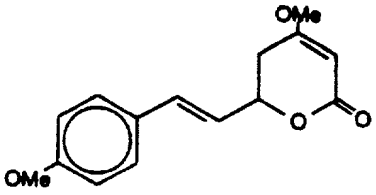
7. Dihydromethysticin



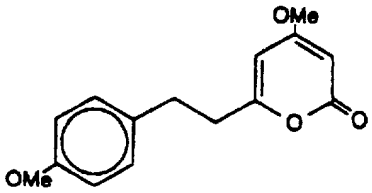
8. 5,6-Dehydromethysticin



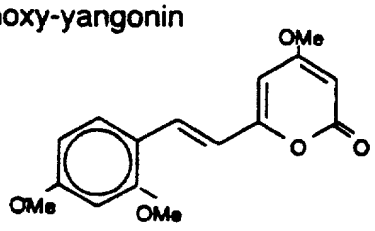
9. 5,6-Dihydroyangonin



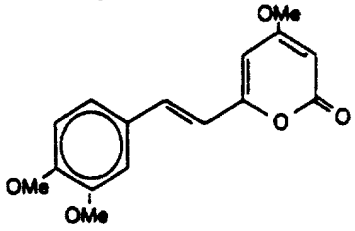
10. 7,8-Dihydroyangonin



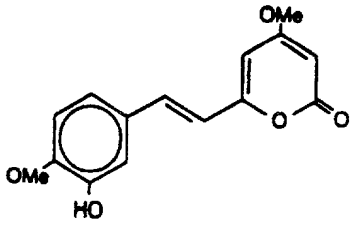
11. 10-Methoxy-yangonin



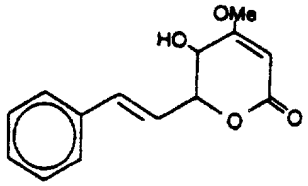
12. 11-Methoxy-yangonin



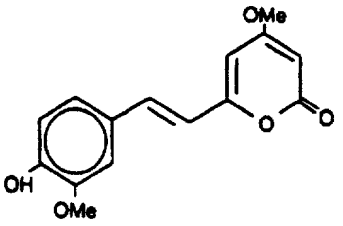
13. 11-Hydroxy-yangonin



14. Hydroxykavain



15. 11-Methoxy-12-hydroxy-dehydrokavain



All of these alpha-pyrones compounds are per se known to this art.

The anticraving effects of kavapyrones are mediated through the dopaminergic neurons of the nucleus accumbens in

the mesocorticolimbic dopamine reward system. This system is not only responsible for the craving of substances of abuse but is also the same mechanism that produces natural motivation for food, water, sex etc. When kavapyrones are administered in vivo by microdialysis into the nucleus accumbens, increasing doses of kavapyrones produces increased levels of dopamine (Baum, 1998). The kavapyrone desmethoxyyangonin produces an increase in dopamine while the kavapyrone yangonin decreases dopamine to undetectable levels (Baum SS et al., 1998). It is through the mesocorticolimbic dopamine reward system kava increases dopamine in pathways which produce euphoria and an anticraving effect by acting as an antagonist for those dopaminergic neurons responsible for acute craving and its effect on 5-HT (Baum SS et al., 1998).

Kavapyrones are known to influence the function of GABAA receptors. It is through the influence on the GABAA receptor that kava produces anxiolytic effects similar to alcohol, benzodiazepines and barbiturates. However, alcohol, benzodiazepines and barbiturates are known antagonists of NMDA while kava is an agonist (Walden J et al., 1997). This finding supports the fact that kava produces either a mildly stimulating or a mildly sedating effect depending on the preparation and dose. It is also this difference that explains why kava produces little effects on mental and motor function and seldom causes intoxication.

The alpha-pyrone compounds are preferably employed in doses ranging from approximately 5 mg to 600 mg every three to four hours depending on the severity of the craving, the specific alpha-pyrone and the weight of the patient.

Alpha-pyrones known as kavapyrones are present in the plant Piper methysticum. The kavapyrones may be extracted using one of a number of known extraction techniques. These compounds may also be synthesized according to a variety of processes described in the literature.

A physiologically accepted medium used to carry an effective amount of alpha-pyrone can be an inert carrier such as in pill form or as a gum. The physiologically accepted medium used to carry the effective amount of alpha-pyrones in a transdermal patch requires the addition of organic solvents to facilitate transport of the alpha-prone across the skin for systemic distribution.

Addictions are complex physiologic and psychological disorders that require treatment of both the mental and physical aspects of the addiction for success. In alcoholism, it has been found most ideal to not only treat the craving for alcohol but to also satisfy the patients desire for the taste, the feeling and the act of drinking. For this reason a novel aspect of the invention involves the addition of an effective amount of alpha-pyrones to non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled sprits. In this manner the taste, experience and a similar feeling is achieved when

drinking the non-alcoholic alpha-pyrone beverage. When an effective amount of alpha-pyrone is substituted for alcohol in beer, wine or distilled sprits patient compliance improves along with the reduction in craving and an improved abstinence from alcohol.

In clinical trails 80% of alcoholics report a resolution of craving for alcohol. In trials for tobacco, cocaine and heroine 100% of the respondents reports a reduction in their craving after consuming an effective amount of alpha-pyrones.

In a double blind placebo controlled study of alcoholics, patients receiving an effective amount of alpha-pyrone achieved abstinence form alcohol more frequently than those taking the placebo (P=.05).

The most effective physiologically acceptable medium used to carry an effective amount of alpha-pyrone for the treatment of the cravings of alcoholism has been found to be non-alcoholic beverages that mimic the taste, appearance and effect of alcoholic beverages. In this instance the alcoholic patient is not deprived of the enjoyment of his/her beverage of choice and is not required to alter his/her social habits while abstaining form alcohol. The addition of an effective amount of alpha-pyrone for the treatment of craving to non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled sprits provides an ideal delivery medium which produces muscle relaxation, stress reduction, mild euphoria and a reduction in the craving for the substance of abuse.

What is claimed is:

1. An administered anticraving composition of matter, comprising an anticraving effective amount of at least one alpha-pyrone compound having the structural formula in which R1 is a hydrogen atom or an alkoxy radical having 1 to 4 carbon atoms, R2 is a hydrogen atom or a hydroxyl group, and R3 is an alkyl radical having from 1 to 4 carbon atoms or a styryl or phenethyl radical optionally substituted by one or two methylenedioxy radicals or one or two hydroxyl groups and/or one or two alkoxy radicals having from 1 to 4 carbon atoms, with the proviso that, when R2 is a hydroxyl group, then R3 is necessarily an unsubstituted phenethyl radical, with the future proviso that when R3 is an alkyl radical having 1 to 4 carbon atoms, then R1 and R2 cannot both be hydrogen, in a physiologically acceptable carrier medium.

2. The composition as defined by claim 1, wherein said alpha-pyrone compound is one or more of the alpha-pyrones found in the plant Piper methysticum.

3. A composition as defined by claim 1, comprising a pill.

4. A composition as defined by claim 1, comprising a gum.

5. A composition as defined by claim 1, comprising a transdermal patch.

6. An orally administered composition producing alcohol like effects in a beverage designed to look and taste like an alcoholic beverage comprising an effective amount of at least one alpha-pyrone compound having the structural formula in which R1 is a hydrogen atom or an alkoxy radical having 1 to 4 carbon atoms, R2 is a hydrogen atom or a hydroxyl group, and R3 is an alkyl radical having from 1 to 4 carbon atoms or a styryl or phenethyl radical optionally substituted by one or two methylenedioxy radicals or one or two hydroxyl groups and/or one or two alkoxy radicals having from 1 to 4 carbon atoms, with the proviso that, when R2 is a hydroxyl group, then R3 is necessarily an unsubstituted phenethyl radical, with the further proviso that when R3 is an alkyl radical having 1 to 4 carbon atoms, then R1 and R2 cannot both be hydrogen.

7. A composition as defined by claim 6, comprising a non-alcoholic beer.

8. A composition as defined by claim 6, comprising a non-alcoholic wine.

9. A composition as defined by claim 6, comprising a non-alcoholic distilled spirit.

ABSTRACT

Administered anticraving compositions are disclosed for treating patients with addictions comprising an effective amount of at least one alpha-pyrone compound formulated into a physiologically acceptable carrier medium. Additionally, novel compositions are disclosed as substitutes for alcoholic beverages comprising an effective amount of at least one alpha-pyrone compound formulated into a non-alcoholic beer, non-alcoholic wine and non-alcoholic distilled spirits.

Baum SS, Hill R, Rommelspacher. Effect of kava extract and individual kavapyrones on neurotransmitter levels in the nucleus accumbens of rats. Prog Neuropsychopharmacol Biol Psychiatry 1998 Oct;22(7):1105-20

German Commision E monograph on Kava

Jamieson DD, Duffield PH. The antinociceptive actions of kava components in mice. Clin Exp Pharmacol Physiol 1990 Jul;17(7):495-507

Kretzschmar R, Meyer HJ. Comparative studies on the anticonvulsant activity of the pyrone compounds of Piper methysticum Forst. Arch Int Pharmacodyn 1969;177:261-267.

Lebot V, Merlin M, Linstrom L. Kava the Pacific Drug. New Haven, CT: Yale University Press; 1992:10

Norton SA, Ruze P. Kava dermopathy. J Am Acad Dermatol 1994 Jul;31(1):89-97

Seitz U, Schule A, Gleitz J. [3H]-monoamine uptake inhibition properties of kava pyrones. Planta Med 1997;63:548-549.

Uebelhack R, Franke L, Schewe HJ. Inhibition of platelet MAO-B by kava pyrone-enriched extract from Piper methysticum Forster (kava-kava) Pharmacopsychiatry 1998 Sep;31(5):187-92

Volz HP, Kieser M. Kava-kava extract WS 1490 versus placebo in anxiety disorders in a randomized placebo-controlled 25-week outpatient trial. Pharmacopsychiatry 1997;30:1-5

Walden J, von Wegerer J, Winter U, Berger M, Grunze H Effects of kawain and dihydromethysticin on field potential changes in the hippocampus. Prog Neuropsychopharmacol Biol Psychiatry 1997 May;21(4):697-706

Warnecke G. Psychosomatic dysfunctions in the female climacteric. Clinical effectiveness and tolerance of Kava Extract WS 1490 Fortschr Med 1991 Feb 10;109(4):119-22

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PTO/SB/01 (12-97)
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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	
First Named Inventor	GREGORY GENE STEINER
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"Alpha-pyrone compositions for controlling craving and as a subsitute for alcohol."

(Title of the Invention)

the specification of which
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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Application Number(s)	Filing Date (MM/DD/YYYY)	
60/141,805	6/29/99	☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*
OR
☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
GREGORY	STEINER

Inventor's Signature	*Gregory Steiner*					**Date**	6-12-00
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☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto